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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,564

01/06/2006

Hisashi Sakamoto

10873.1791USWO

3665

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7590

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EXAMINER

WHITE, DENNIS MICHAEL

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

07/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,564	Applicant(s) SAKAMOTO ET AL.	
	Examiner DENNIS M. WHITE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/09/2006, 06/03/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to the metes and bounds of the claim because on line 7, the "balance pad is provided on the holding portion side in the reagent pad arrangement region," whereas on line 3 the "holding portion" and "reagent pad arrangement region" are described as separate portions ("portion other than"). How can the balance pad be in the holding portion and in the reagent pad arrangement region if the holding portion is a portion "other than" the reagent pad arrangement region?

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Engelmann et al (USP 4,837,043).

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Regarding claim 1, Engelmann et al teach a diagnostic test strip ("a sample analysis tool") comprising: a substrate (Figure 2:3); and a reagent matrix portion ("at least one reagent pad provided on the substrate") (Figure 2:5), and a elevated portion ("wherein a balance pad is provided on the substrate") (Figure 2:4). The elevated portion is fully capable of adjusting at least one of weight balance and friction balance of the sample analysis tool.

Regarding claims 2-4, Engelmann et al teach the diagnostic test strip ("the substrate is in a strip shape") (col.4 line 1), and one end portion of the substrate is fully capable of serving as a holding portion (Figure 2: side opposite 5) which comprises the elevated portion ("the balance pad is provided on the holding portion side in the reagent pad arrangement region" "the balance pads is in a range of 1 to 3") (Figure 2:4) and a portion other than the holding portion serves as a reagent pad arrangement region ("the at least one reagent pad is provided on a side opposite to a holding portion side in the reagent pad arrangement region" "reagent pads is in a range from 1 to 8") (Figure 2:5).

Regarding claims 5-7, Engelmann et al teach the test strip can contain one or more reagent zones and usually contain different reagents for the detection of various substances ("wherein two or more reagent pads are arranged in series along a longitudinal direction of the strip-shaped substrate") (col. 4 line 1-7) such as urine test strips contain reagent zones for glucose, pH, ketone, bilirubin, nitrite and hemoglobin zones ("a urinalysis" "glucose (GLU), protein (PRO), bilirubin (BIL), pH, ketone bodies (KET), nitrite (NIT), and at least one reagent pad is provided for each test item").

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Regarding claim 8, Engelmann et al teach the color intensities were observed corresponding to the increasing glucose contents ("which is analyzed by an analyzer") (col.6 lines 37-40 and col. 7 line 46-47).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

dmw

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797